Section V. Policy Issues in the Use of Animals in Research, Testing, and Education

L ublic policy about the use of animals in research in the United States acknowledges that animal experimentation is a needed part of science and that it must be conducted in accord with certain humane standards. National policies require registration and inspection of facilities, compliance with specified husbandry standards, and efforts to minimize animal pain, among other provisions. However, inadequate attention is given in existing policy to the ethical justification of research protocols involving animals, including standards to distinguish between acceptable and unacceptable animal experiments. The degree of public concern over questionable or unjustified experiments suggests that public policy should more thoroughly address attention to justification standards.

Justifying an Animal Experiment

Each animal experiment that involves pain, death, or holding captive a sentient creature poses the issue of justification. The harms to the animal conflict with perceived societal benefits that will result if the experiment is conducted. This conflict can be resolved by seeking the best possible reconciliation of human needs with concern for the needs and well-being of all other animals.

As discussed in Section II, decisions to approve or disapprove any individual experiment, a task of the Institutional Animal Care and Use Committees (IACUC) mandated by federal law, are often very difficult to make because of the need to take into account several different issues, some of which are schematically presented in Figure 2. Among the major criteria

for assessing justification of an experiment are: 1) the purpose of the experiment (including its social merit); 2) the sentience level of the subject of study (including philosophical consideration of the moral status of the animal, which is, roughly speaking, greater the higher up the phylogenetic scale one goes); 3) severity and duration of animal pain; 4) the competency of the experimenter; 5) the application of "alternatives" to improve the justification; 6) the quality of the facility and resources where the work is conducted (this to some extent reflects the excellence of the husbandry standards); and 7) the level of public accountability.

Applying these criteria creates a complicated decision-tree. Each decision must take into account the weight to be given each criterion and how the many intertwining and often conflicting factors are to be resolved. A decision to approve or disapprove a particular experiment ultimately depends on the decisionmaker's value judgments.

Nor are these criteria allencompassing. Several others could be added to cover matters such as the previous life history of a particular animal, a group of animals, or species; whether dogs or cats obtained from pounds, which have been prior household pets, should ever be used, or be used just for limited purposes such as acute experiments, or whether purpose-bred animals should be substituted; whether a non-human primate intended for experimentation is wildcaught or purpose-bred; whether the species as a whole is endangered (such as chimpanzees used sometimes in research and testing); or whether the conditions under which

primates and other species are housed fulfill the psychological needs and permit natural expression of the behavioral repertory of that species.

In the following discussion, we will concentrate on three central criteria—the purpose of the experiment, animal pain, and applying alternatives—while others that are fairly self-evident are mentioned only where particularly relevant.

The Different Goals of Research, Testing, and Education (Criterion 1)

Biomedical research is undertaken for two broad purposes, to add to scientific understanding of basic biological functions, processes, and behavior (basic research), or to improve human or animal health by studying the natural history of disease, its pathophysiology and prevention, and by developing diagnostic and therapeutic methods (applied research). These are important and worthy goals. Public attitudes are such that, compared with other uses of animals, the use of animals for research (both basic and applied) would be granted the greatest sanction. Presumably, the public would tolerate a greater degree of animal pain for the purpose of research than for either testing or for education.

Testing is conducted to assess the potency, effectiveness, or toxicity of substances of established or potential usefulness for medical, scientific, or commercial purposes. For instance, by law, new drugs are tested for efficacy and safety on several species of animals prior to conducting clinical trials on humans. In addition, tests on animals are conducted to establish safety levels for humans of known toxic substances (for instance, those that occur as human hazards in the chemical production industry or as environmental pollutants from toxic waste deposits). Justification for these tests is based on the reasonable assumptions that adverse effects caused by chemical substances in animals are usually the same as those encountered in humans, and that the dose causing toxicity in animals permits risk assessment for exposed humans. So long as one accepts some animal experimentation, there are sound reasons to support some

Figure 2 Illustrative Sets of Criteria for Assessing Justification for Animal Experiments

	Justification for	Animal Experiments	
Purpose of experiment ¹	Classification of sentience level	Animal pain³	Competency of experimenter
to gain original knowledge (high social worth)	non-biological systems e.g., computer simulation little or no sentience e.g., protozoa and plants	rone	highly skilled persons with years of training in science and humane techniques
for product safety and drug testing ¹	less sentient invertebrates e.g., worms, insects highly sentient invertebrates e.g., octopi	- invertebrate animal pain	- post Ph.D.
for professional training	- cold-blooded vertebrates (fish, amphibians, reptiles) - warm-blooded	- some short-lasting vertebrate animal pain	graduate level
for other educational purposes ²	vertebrates (birds, mammals) - non-endangered primates and marine mammals endangered primates and marine mammals	significant but unavoidable vertebrate animal pain4	elementary and secondary school level, novices of all educational levels
Alternative methods for improving justification	Quality of facility and resources where work done	Public accountability	LEGEND
application of three "Rs" of refinement, replacement, and reduction	facilities subject to federal oversight and meaningful inspection for humane concerns (USDA, PHS)	facilities with federal oversight (USDA, PHS, or FDA) that is effectively enforced	The bars represent several criteria for assessing justification for animal experiments; competency of experimenter, purpose of experiment, degree of animal pain, and sentience level of organism used tems placed at the top of the bar indicate the situations where there is the greatest or most readily conceded justification. Those at the bottom of the bar carry the least justification or alternatively are those situations most vulnerable to improper use of animals.
	- universities and industrial research labs	activities involving animal experiments that are open to state or other official inspection and oversight	NOTES 1. Experiments involving animal pain or death conducted for trivial purposes, for mere curiosity, or for repetition of well-known facts are disallowed. 2. A distinction must be made between educational projects involving animals that carry no ethical costs (i.e., do not involve harm or death of a sentient animal) that should be encouraged, and those that do carry an ethical cost that should be discouraged. However, as a general principle, study of living organisms is essential to
no effort to apply three "Rs"	_ other	. other	sound biology education. 3. See also detailed pain scale in figure 3 (categories A-E) 4. Note that severe pain is disallowed.

animal testing. Nevertheless, some animal tests, especially safety tests on cosmetics and household products such as oven cleaners, have been a primary target of public protests. Activists and critics have argued that some procedures are unnecessarily painful to the animals and should be eliminated, that alternative tests exist, and that, in any case, some of the products being tested are nonessential or of trivial social worth.

In education, animals are used to teach humane concepts at all levels of education, and also to instruct students of the biological sciences in biology, physiology, pharmacology, and surgery. Student biology projects are by their very nature repetitive, because their objective is to teach the student established facts about fundamental biological principles; similarly, pedagogical repetition may be required in professional schools to teach certain skills like surgery. The purpose is not to make original contributions to knowledge. There is thus little significance in the actual experimental results obtained, in contrast to research and testing where the results are all-important

The social worth of advanced educational projects involving animals is that a next generation of scientists are trained—a reasonable and socially valuable objective. However, an increasingly large segment of the population is convinced that these objectives can be achieved without resorting to harming and killing animals.³¹

United States policy regarding use of animals has been largely devised with research in mind. Nevertheless, the policies usually state that they are applicable in research, testing, and education alike and distinctions between these situations are not addressed. For instance, the Public Health Service (PHS) policy (one of the two systems of national policy) includes important basic principles that specifically designate their applicability "in testing, research, and education."47 Similar phrases exist in the Animal Welfare Act, the federal law governing humane use of laboratory animals and the second system of national policy.

Future revisions of national policy should specifically address the significance of different contexts and goals, rather than, as at present, treating research, testing, and education as all equally justifiable and governed by the same rules.

Gaps in the coverage of facilities. The net of national policy does not, however, fall equally on institutions involved in the three practices of research, testing, and education. In general, most research institutions are covered by some national policy, while testing facilities and educational establishments often fall outside both the PHS policy and the Animal Welfare Act.

These gaps in coverage occur in the following manner. The PHS policy applies only to recipients of federal funds for animal experiments. Thus, many academic research institutions are covered under the PHS policy but, on the whole, commercial facilities that conduct research, such as pharmaceutical companies, are not. PHS policy also does not apply to testing facilities because these are overwhelmingly commercial enterprises that receive no PHS funds.

The Animal Welfare Act requires registration and federal inspection of facilities where non-human primates. dogs, cats, guinea pigs, hamsters, rabbits, and other warm-blooded animals except rats and mice are used for experimentation. The exclusion of rats and mice means that approximately 90 percent of laboratory animals are not protected by AWA, in contrast to PHS policy. The Act covers many research institutions, both academic and commercial, but a few are exempt because they use only excluded species. Moreover, the exclusion of rats and mice effectively exempts most testing and many educational facilities.

Although certain regulations ("Good Laboratory Practices") do apply to the use of animals in testing, these are aimed at ensuring the efficiency and accuracy of the tests and do not address animal welfare directly. In the many testing facilities that use only rats and mice, there is no official mechanism for oversight of animal housing conditions, no provisions for personnel training, nor are the protocols subject to review by an IACUC. What good standards as do exist stem largely from in-house

quality control established by the commercial company itself.

The use of animals in education is barely touched by any effective oversight. The Animal Welfare Act specifically excludes elementary and secondary schools, and the PHS policy does not apply because the federal funds that do go to education are not from the PHS.

Expanding coverage to rats and mice. It is an anomaly peculiar to the United States that rats and mice are excluded from the Animal Welfare Act. Correcting this would have important institutional repercussions by bringing additional facilities (especially testing and educational facilities) within the scope of the law and would tend to eliminate unsuitable facilities (such as high school students' homes) that are currently used for painful animal experiments. The impact would be felt, in addition, at educational facilities such as community and other colleges that presently have no effective oversight. For the first time, they would be subject to federal inspection.

Including rats and mice in AWA would have some impact on research institutions, but this would be moderated by two facts. Many research institutions currently fall under the jurisdiction of PHS policy that covers all vertebrate animals including rats and mice, and, moreover, some research institutions already voluntarily include rats and mice in their institutional animal welfare policies. Even so, expanding the scope of federal law to include these sometimes despised but highly sentient creatures would have important symbolic and practical effects.

Animal Pain (Criterion 3)

Revising federal policy to include a classification system of experimental procedures according to the degree of animal pain would help address several problems. It would provide a scale for judging ethical cost in cost/benefit assessments; it would provide a concept for development of policies governing the use of animals in education (see discussion below); and it would encourage acceptance of the idea that some procedures are totally unacceptable

Figure 3

Categories of Biomedical Experiments

Based on Increasing Ethical Concerns for Non-Human Species¹

Category A	Category B	Category C	Category D	Category E	
either no living materials, or plants, bacteria, protozoa, or invertebrate animal species	Vertebrate Animal				
	little or no discomfort	some discomfort (short-lasting pain)	significant but unavoidable distress or discomfort	extreme and intolerable pain in conscious animals; severe deprivation, trauma, mutilation	

¹Adapted from Table 1, Orlans, "Research Protocol for Animal Welfare." See reference 30.

(even though there remains controversy over exactly which procedures these are). There is good reason, therefore, to adopt such a system. In practice, many IACUCs have found a classification of animal pain surprisingly easy to apply and of great use in facilitating protocol review.

Classification schemes. The several scales currently in existence1,27,29-30,42 all share a similar concept of denoting increasing ethical cost with regard to the pain or suffering of the animal. A number of countries have already adopted such a policy, including the United Kingdom, Sweden, the Netherlands, Canada, and New Zealand. The five-point classification system (Figure 3) has been incorporated into national policy both in Canada and New Zealand. This classification was also recommended as official policy in the United States in the USDA's proposed rules of 1987, (Federal Register, March 31, pages 10313-14) but was subsequently rejected. There is a good chance that a similar proposal will be made again in the future with more success.

In addition to the advantages already mentioned, there are other benefits of having a classification system for animal pain included in national policy. Detailed discussion of these fall outside the scope of this

section, but such benefits can be listed. Practical uses include sensitizing investigators to how much animal pain is involved in any procedure by requiring them to classify their own experiments; indicating to the oversight committee the depth of review needed (for instance, those procedures involving little or no pain could be given expedited review, whereas procedures falling in category D or E would be given stringent review); and providing a system for national data collection on animal experimentation to enhance public accountability.

In applying the "pain scale," it obviously matters which species of animal is the subject of the pain. There are, thus, important cross links between the severity and duration of pain (criteria 3, Figure 2) with the sentience level of the species (criteria 2). Non-human primates are afforded a special status in the hierarchy of animals inasmuch as they have the most complex and highly developed nervous systems, are most capable of experiencing pain and distress, and are genetically most similar to human beings. (Chimpanzees share 98 percent of their genetic material with man.) It follows that inflicting pain on non-human primates carries significant ethical cost

Unacceptable procedures. There are some particularly egregious procedures which, irrespective of the scientific merit of the experiments, ought to be judged unacceptable because of the intensity of animal pain, at or near tolerance level (see category E, Figure 3). A concept of some procedures being beyond ethical justification has become widely accepted in human experimentation, and is gaining adherents in animal experimentation.

In the process of justifying an animal experiment, a sequence of decisions must be made. First, it is necessary to raise a threshold question of whether the procedure is unacceptable. Is it justified to put animals into condition x, which will result in pain y, irrespective of any benefits that might be anticipated? Thus, we can ask if it is ever justified to blow-torch pigs, regardless of how much we stand to learn about burns. Only when this threshold question has been raised and answered affirmatively, can we then proceed to the second question of whether this particular form of animal experiment can be justified. The criteria described in Figure 2 are applied at this second

It seems reasonable that cut-off points for unacceptable procedures

would differ depending on whether the animals are used in research, testing, or education. For instance, junior students ostensibly should be restricted to categories A and B, while for more advanced college students the boundary should be category C. Most testing and research work can be conducted within categories A, B, and C; occasionally there may be justification for category D experiments. Even for research and testing, many hold that no category E experiment should be conducted. Certain testing procedures judged too traumatic to sanction could be identified as falling within category E. Public policy inclusion of a general concept of "unjustified under any circumstances" would go far in sensitizing scientists to the ethical limits of permissible animal experimentation.

Application of Alternatives (Criterion 5)

A brief explanation is necessary regarding "alternative methods for improving justification." "Alternatives" represents an attitude of mind. It means that, prior to starting any procedure, a meaningful search should be made to find ways to accomplish the same ends with less harming or killing of animals. As mentioned in Section II, three major approaches are used either severally or together. One is refinement of the procedure to reduce the amount of animal pain or distress. (The concept of refinement can be easily conveyed by reference to Figure 3. The objective is always to shift toward a lower category, for example from D to C, or C to B, etc.). A second is reduction of the number of animals used, and a third is replacement of animal studies with non-animal systems. These three approaches have proved to be remarkably useful in fostering humane concepts and practice.

Unfortunately, the concept of alternatives is sometimes distorted by the presentation of only one aspect (replacement) rather than all three. For instance, scientists who argue against replacement of animal experimentation (and cogent reasons can be given to support this view) may

infer from these arguments that the concept of alternatives as a whole is flawed. However, their claims neglect the refinement and reduction options.

Certain patterns can be seen in the application of alternatives in research, testing, and education. In research, the state of the art is such that refinements are the most readily available option. Indeed, effective IACUCs expend considerable effort in applying refinements. In testing, all three approaches are available for immediate application and already have had beneficial effects. There has been progress in stopping some animal tests conducted for trivial purposes, and some advance in substituting tissue culture and other alternative methods that considerably reduce the numbers of animals used.

The greatest opportunities for application of alternatives in the use of animals exist in education. A strong case can be made for immediately eliminating certain experiments: for instance, those involving infliction of vertebrate animal pain by precollege students. Any detriment to education from this restraint is highly questionable. Indeed the prohibition would diminish the chance of developing an insensitive attitude toward harming and killing. Other important opportunities exist at all levels of education to replace pain-inflicting vertebrate animal experiments either with those that cause no pain, or with projects using species with lower levels of sentience, such as invertebrates, or protozoa. All this can be achieved while encouraging the study of living organisms in education, including observational studies of vertebrate animals.

In a welcome and important move in 1989, the National Association of Biology Teachers announced official support of alternatives "to dissection and vivisection" and are currently preparing materials to help educate teachers on these matters.

Practices and Problems in the Use of Animals in Education

Historically, the use of animals in education has been the least controlled. No agreed-upon national standards exist, and, on the whole, policies governing the use of animals in education are poorly developed. A few voluntary guidelines exist, ranging from permissive to reasonably stringent, but there is no consensus, and no effective mechanism for enforcement. This field is wide open for reform.

Until recently virtually all college student work involving animal pain or death has fallen outside the purview of any effective review for humaneness. New regulations of the Animal Welfare Act require student activities conducted at USDAregistered facilities to be reviewed by IACUCs. These regulations, published in the Federal Register on October 31, 1989, have broad implications, because for the first time there is a mandate that student work be subject to oversight committee review. This heralds the start of longoverdue improvements in the use of animals in education.

At the state legislative level, a handful of states have enacted legislation to control the abuse of animals in secondary school projects. The purpose of these state laws is to restrict untrained youth from inflicting pain and lingering death on vertebrate animals in the name of science. These laws have come about because of strong public protests against appalling experiments found in secondary school science competitions commonly called "science fairs," which are extracurricular projects where students compete for monetary prizes. Typical science fair projects of the 1960s and 1970s included crude attempts at animal surgery on monkeys, rabbits, and other animals, often conducted in the unsuitable conditions of the teenagers' homes. Other projects have included the blinding of sparrows, which were then starved to death, and the administering of well-known toxic substances to pregnant animals to see how many dead or deformed babies were born. Such projects have won prizes, thus exacerbating the continuance of inhumane standards.

As a result of the sparrow blinding project in 1969, the Westinghouse Science Talent Search immediately changed its rules for competition. Previously, the rules had permitted infliction of animal pain, but since

then, projects other than observational studies of vertebrate animals have been forbidden. Other competitions, however, have not followed suit. Yet by the schema of Figure 2, and to common ethical sense, teenage biology projects involving pain or lingering death seem among the least justifiable of animal uses.

Public protests have now moved decidedly beyond high school science competitions. Many students themselves are refusing to participate in projects involving harming or killing animals. The protests run the gamut from young high school students who refuse to dissect frogs, to veterinary students who refuse to induce pathological conditions in healthy dogs and cats, to medical students who refuse to practice surgery on dogs and goats.

Patterns of animal use in education. In the elementary school, live animals are brought into the classroom for the primary purpose of humane education, but they are pets and not laboratory animals. In secondary schools curricula, few live vertebrate animals are used in the classroom, but many dead frogs are used for dissection. Currently, some 75 percent of junior and senior high schools conduct frog dissections. In high school science competitions (as distinct from classroom projects) considerable animal experimentation exists, some of which is highly invasive, falling under categories C, D, and E in Figure 3. At the college level in biology courses, some dissections of dead animals and some projects involving live turtles, frogs. rats, mice, and other small mammals occur. In medical and veterinary schools, live dogs and cats are sometimes used to demonstrate fundamental physiological responses, common drug reactions, and for practice surgery (such as removal of certain organs). Most commonly, these exercises are conducted by, or under the direction of, a fully qualified supervisor, and the experiments are "acute"—that is, the animals are fully anesthetized and never recover consciousness. "Acute" experiments are more humane than "chronic" ones because, if properly done, the animals will not suffer any pain whatsoever. The ethical cost lies in the death of the animal.

In other pedagogic exercises in both medical and veterinary schools, pathological conditions may be induced in healthy dogs and cats for practice as part of the students' professional training. The ethical cost can be high in these situations because the exercise is often "chronic" so that the students may follow the course of the pathological condition. This is done instead of studying and treating an already sick person (for medical students), or client animal (for veterinary students). There is increasing pressure for students to study the course of naturally occurring pathological states in the subjects they will eventually be treating. At issue then in assessing the justification of a particular educational exercise is the educational needs of those students. whether the experiment is "acute" or "chronic," whether the pathological condition is induced or naturally occurring, and the availability of alternatives to teach the same or similar lessons.

Recommended National Policy for the Use of Animals in Education

Policies for the use of animals in education should be based on concepts shown in the pain scale (Figure 3). Novices should begin with category A procedures (non-vertebrate animal projects). Only as their educational level advances should permission be granted to progress to category B (vertebrate animal projects involving little or no discomfort). Thus, secondary school student projects arguably should be confined to category A and B procedures. College-level students could be permitted to conduct A or B procedures and may, if committed to a career in science, conduct C procedures (vertebrate studies involving short-lasting pain). At some point in a student's training, the goal of the experiment switches from educational to real research in which there is potential acquisition of original knowledge. Most commonly this occurs at the graduate school level. In any particular instance, judgment on this must be left to the student's supervisor and the IACUC. Category D procedures (significant pain) should be reserved for

research. Such procedures should only be conducted by persons who are highly qualified as scientists and who have received training in humane techniques. Adoption of such a concept would help eliminate the more unacceptable practices still encountered in science competitions.

Enforcement of policies governing the use of animals in education can be effected in various ways. If national policy that required eliminating the infliction of pain on vertebrate animals in elementary and secondary schools were accepted, then the schools themselves and especially the science fairs would need to monitor compliance. Furthermore, any student project involving the infliction of vertebrate animal pain or lingering death would be required to be conducted in a facility that has a mandated IACUC. Finally, expansion of the Animal Welfare Act to include rats and mice would provide oversight to educational establishments that now fall outside the law.

Needed Directive

The Animal Welfare Act of 1966 and its strengthening amendments, along with the PHS policy, have served to improve humane standards for laboratory animals. The beneficial effects have fallen mainly on animals used in research. Still, several important refinements in public policy should be made in the use of animals for research. Moreover, it is now time to improve the policies covering animals used in education and in testing. Immediate attention needs to be given to devising and implementing policies on the use of animals in education. Steps in these directions would help establish humane standards that are in keeping with the public's ethical concerns.

—F. Barbara Orlans.

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Future Directions

In this Special Supplement, we have tried to emphasize the points of consensus that the project participants of "The Ethics of Animal Experimentation and Research" in fact reached: that the use of animals in science involving animal suffering or harm is decidedly an ethical issue; that the greater the ethical cost is to the animals, the more compelling is the justification required; and that at some point we perhaps move beyond the limits of ethical justification.

However, we also stressed that "animal ethics" is actually in its early stages and that there is still much work to be done, especially concerning the fundamental issues. With respect to the moral status of animals and ethical theory, we need to examine further the relative ethical significance that we should accord to animal pain, distress, and suffering versus the natural capacities of animal life and activity. This should be conjoined with the elaboration of a philosophically and ethically adequate conception of "animal hierarchy." We also need to face the plurality of ethical theories and decide whether to accept traditional ethical articulations or to press on to more adequate and comprehensive theories. Further, we should decide whether we will accept principled "trumping," or absolutist ethical stances or whether we must look at particular cases and their conflicting values, the so-called "moral ecology," on their own merits.

With respect to animal suffering, we noted the limitations and openended character of the method of critical anthropomorphism. A further, though controversial approach to understanding animal suffering is an exercise in philosophical, speculative imagination. This involves an attempt to understand what is required for any being, human or animal, to be able to suffer in the most emphatic, "personal" sense of the term, as

distinct from experiencing pain or distress.

Arguably such suffering at least requires a concrete, organic individual or self, with a genuine and conscious sense of the past, present, and future, and with capacities both for images or ideas and for life plans or more immediate goals that can be frustrated. When the individual self's vulnerable, subjectively felt integrity ("oneness") is actually or potentially threatened, the individual being suffers, as opposed to merely feeling pain.9 The future philosophic task, espoused by Eric Cassell, among others, is to give an adequate speculative account of a "suffering being," to identify those animals (if any) capable of such suffering, and finally to decide what relative ethical status to give the suffering individual.

Yet of all the unfinished business, none is more pressing than the need to "take together" and to consider systematically our ethical responsibilities to human beings, animals and animate life, and the environment. Parochial, adversarial interests and the lack of a wide coordination in our ethical thinking sooner or later will lead to disasterous practical consequences for both human communities and individuals and the wider animate realm. It is our ethical responsibility to avoid such moral failure.

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255 Elm Road Briarciiff Manor, NY 10510

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